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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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WASHINGTON, DC 20004

EXAMINER
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HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/761,237

Applicant(s)

WENDEL ET AL.

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/22/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 08/966,768.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/22/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Amendment Entry***

1. The amendment filed January 22, 2004 has been entered. Claims 1-18 have been cancelled. Claims 19-22 have been newly added. Claims 19-22 are under consideration in this office action.

### ***Priority***

2. If applicant desires benefit of a previously filed application under 35 U.S.C. 119, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence(s) of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

### ***Information Disclosure Statement***

3. The information disclosure statement (IDS) submitted on January 22, 2004 was filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Specification***

4. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

#### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading.

#### **(Content of Specification)**

- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.
- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.
- (d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).
- (e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.
- (f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
  - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of

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the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

- (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.
- (h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation.

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There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

- (k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "standardized blood unit dose" in claims is a relative phrase which renders the claim indefinite. The phrase is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There is no teaching of how the standardization occurs or by whom the standardization is determined. Thus, the metes and bounds of the phrase are unclear and appropriate clarification is required to overcome the rejection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Rubinstein et al., (PNAS, 1995. Vol. 92, pages 10119-10122).

The claims are drawn to methods of testing a material or object for human applications by detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against the material or object, the method comprising the steps of (i) contacting said material or object with a blood sample from a human or animal and (ii) detecting and/or measuring the immunofunctional, toxic, or modulatory blood reaction by a biological, physical, chemical, or physicochemical method, wherein the improvement comprises using as the blood sample a thawed cryopreserved unit of whole blood, said cryopreserved unit (a) being selected from the group consisting of a plurality of identical cryopreserved units from one lot of a whole blood sample, (b) being in the form of a standardized blood unit dose, and (c) containing a cryopreservative and/or further comprising clotting inhibitors and/or diluents.

Rubinstein et al., teach processing and cryopreservation of placental/umbilical cord blood for unrelated bone marrow reconstitution. Placental/umbilical cord blood was retrieved and contained in blood donor set containing citrate/phosphate/dextrose/adenine (CPD A) anticoagulant (page 10,120, col.1). The

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dimethyl sulfoxide (DMSO) cryopreservative was added to the blood bag and mixed with isotonic saline (page 10,120, col.2). The CPD A was used in a standard blood transfusion bag (page 10,120, col.2). Thus, the authors teach a blood cryopreserved unit of whole blood containing a DMSO cryopreservative, CPD A anticoagulant clotting inhibitors, and a saline diluent, just as required by the claims. The authors teach thawing of the units for experimental work, thereby teaching a standardized blood unit dose, just as required by the claims. Therefore the authors teach that the blood sample was contacted with a material such as an anticoagulant and cryopreservative, just as required by the claims. The authors teach the performance of statistical test (page 10,120, col.2). Table 2 shows measurements of leukocyte and hematopoietic progenitors in 12 units before freezing and after cryoprotection. Furthermore, the measurements of the effect of the recovery of viable leukocytes and progenitor cells was determined, see Table 3. It is noted that in view of the broad interpretation of any immunofunctional, toxic, or modulatory blood reaction by any biological, physical, chemical or physiochemical method, the measurement of leukocyte and hematopoietic progenitors meets the instantly recited limitation. Therefore, the authors teach detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction by a biological, physical, chemical or physiochemical method, just as required by the claims.

Accordingly, Rubinstein et al., teach methods of testing a material or object for human applications by detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against the material or object, the method comprising the steps of (i) contacting said material or object with a thawed whole blood sample

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containing a cryopreservative, a clotting inhibitor and diluent from a human or animal and (ii) detecting and/or measuring the immunofunctional, toxic, or modulatory blood reaction by a biological, physical, chemical, or physicochemical method, just as recited by the claims.

7. Claims 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaye et al., (J. of Virological Methods, 1991. Vol. 35,pages 217-226).

The claims are drawn to methods of testing a material or object for human applications by detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against the material or object, the method comprising the steps of (i) contacting said material or object with a blood sample from a human or animal and (ii) detecting and/or measuring the immunofunctional, toxic, or modulatory blood reaction by a biological, physical, chemical, or physicochemical method, wherein the improvement comprises using as the blood sample a thawed cryopreserved unit of whole blood, said cryopreserved unit (a) being selected from the group consisting of a plurality of identical cryopreserved units from one lot of a whole blood sample, (b) being in the form of a standardized blood unit dose, and (c) containing a cryopreservative, clotting inhibitors and/or diluents.

Kaye et al., teach the storage and preservation of whole blood samples for detection of HIV by PCR. Kaye teach a method of storage and preservation of whole blood samples in a glycerol/gelatin cryopreservative medium commonly known as Glycigel, such that samples may be stored frozen after sampling and DNA suitable for

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use in PCR extractions up to 3 months later (page 218, para.2). The method allows samples to be stored and transported to a central laboratory where they can be batch processed (page 218, para. 2). Thus, a standardized blood unit dose is taught. Two-ml aliquots of heparinised blood was taken from human donors whereby the blood was mixed with Glycigel, sodium azide and stored frozen (page 218, para. 4). Thus the whole blood sample containing Glycigel cryopreservative and heparin, a clotting inhibitor, and sodium azide as diluent, just as instantly claimed. The methods also teach the performance of PCR using Glycigel samples (page 219, para.3). Therefore, the authors teach that the blood was contacted with Glycigel material, just as required by the claims. It is noted that in view of the broad interpretation of any immunofunctional, toxic, or modulatory blood reaction by any biological, physical, chemical or physiochemical method, the performance of PCR which detects the presence of HIV meets the instantly recited limitation. The methods teach that several units of the donor blood were subjected to identical Glycigel cryopreservative treatment thereby teaching a standardized blood unit containing a cryopreservative (page 218-219, para. 5-2).

Accordingly, Kaye et al., teach methods of testing a material or object for human applications by detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against the material or object, the method comprising the steps of (i) contacting said material or object with a thawed whole blood sample containing a Glycigel cryopreservative, a heparin clotting inhibitor and a sodium azide diluent from a human and (ii) detecting and/or measuring the immunofunctional, toxic, or modulatory

blood reaction by a biological, physical, chemical, or physicochemical method, just as recited by the claims.

8. Claims 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Vora (US Patent 4,774,088).

The claims are drawn to methods of testing a material or object for human applications by detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against the material or object, the method comprising the steps of (i) contacting said material or object with a blood sample from a human or animal and (ii) detecting and/or measuring the immunofunctional, toxic, or modulatory blood reaction by a biological, physical, chemical, or physicochemical method, wherein the improvement comprises using as the blood sample a thawed cryopreserved unit of whole blood, said cryopreserved unit (a) being selected from the group consisting of a plurality of identical cryopreserved units from one lot of a whole blood sample, (b) being in the form of a standardized blood unit dose, and (c) containing a cryopreservative, clotting inhibitors and/or diluents.

Vora teach methods and additives for improving the oxygen off-loading capacity and post-transfusion viability of whole blood and thereby extending the shelf life of blood during normal blood banking (col. 3, lines 40-45). The shelf life of blood is increased by increasing ATP (adenosine triphosphate) and 2,3-DPG (2,3-diphosphoglycerate) levels through the manipulation of red blood cells glycolytic and non-glycolytic enzymes such as pyruvate kinase (PK) during storage (col.3, lines 45-50). In order to improve quality, the preserving compound is either added to the bag containing the 2,3-DPG

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preservative into which blood is drawn directly or is added to the fresh blood immediately after collection into the anticoagulant (col. 8, lines 21-26). Thus the bags provide a plurality of standardized blood unit dose, just as required by the claims. The mixture of whole blood, anticoagulant and the preserving compound is then stored at specific temperatures wherein cryopreservative agents such as glycerol are used when storing at lower temperatures (col.8, lines 30-35). Thus, the authors teach a thawed cryopreserved unit of whole blood containing a glycerol cryopreservative and anticoagulant clotting inhibitors, just as required by the claims. Screening procedures are used to effectively test the efficacy of a number of compounds that may be used as inhibitors of PK during blood banking. Therefore the authors teach contacting the material or object (i.e., the 2,3-DPG compound) with the blood sample, just as required by the claims. The assay measures the rate of formation of radiolabelled  $^{14}\text{C}$ -pyruvate and radiolabelled  $^{14}\text{C}$ -lactate and measures the flux of PK (col. 8, lines 6-10). Thus the measurement of the rate of formation for  $^{14}\text{C}$ -pyruvate,  $^{14}\text{C}$ -lactate and the flux of PK meet the broadly recited requirement of detecting and/or measuring a modulatory blood reaction by a biological, physical, chemical or physiochemical method, just as required by the claims.

Accordingly, Vora et al., teach methods of testing a material or object for human applications by detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against the material or object, the method comprising the steps of (i) contacting said material or object with a thawed whole blood sample containing a cryopreservative and an anticoagulant clotting inhibitor from a human and (ii) detecting

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and/or measuring the immunofunctional, toxic, or modulatory blood reaction by a biological, physical, chemical, or physicochemical method, just as recited by the claims.

### ***Response to Arguments***

9. Applicant's arguments with respect to claims 36-39 of the parent application have been considered but are moot in view of the new ground(s) of rejection.

It is noted, that there is no rejection based on the claims being in Jepson format, therefore applicants arguments drawn to the use of Jepson claims are moot.

Applicants' argue that Wendel and Boyse teach away from the instant claims, however applicants' arguments are not germane because the instant claims have not been rejected under either Wendel and/or Boyse. The instant office action presents new grounds of rejections and the arguments with respect to claims 36-39 of the parent application are moot in view of the new grounds of rejection.

### ***Prior Art***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Boyse et al., (US Patent 5,192,553) teach the preservation of a blood sample comprising cryopreserved units of whole blood comprising clotting inhibitors also known as anticoagulants and diluents just as the instant claims. Judy et al., (US Patent 5,030,200) teach a safe and economical method that will eradicate pathogenic viruses, microorganisms or parasites from human whole blood wherein the

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method admixing an a photoactive compound with a bodily fluid such as whole blood which includes body fluids prior to, or after physical as well as chemical fractionation, separation or freezing so that the treated body fluid is free of contaminants. Scheuning et al., teach complement activation during storage of blood under normal blood bank conditions and determining the effects of proteinase inhibitors and leukocyte depletion from units of whole blood collected from human donors in an anticoagulant.

### ***Conclusion***

11. No claims allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, A. Marc Navarro can be reached on 571-272-0861. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines  
September 25, 2006

A handwritten signature in black ink, appearing to read 'Ja-Na Hines', is written over the printed name.